

Biological Product and HCT/P Deviation Reports –
Annual Summary for Fiscal Year 2012

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I. Summary:

FDA requires reporting of certain deviations and unexpected events in manufacturing in accordance with 21 CFR 600.14, 606.171 or 1271.350(b). Manufacturers of licensed biological products other than blood and blood components (licensed non-blood) who hold the biological product license for and had control over the product when a deviation or unexpected event occurred are required to submit Biological Product Deviation (BPD) reports (21 CFR 600.14) to the Center for Biologics Evaluation and Research (CBER), if the safety, purity, or potency of a distributed product may be affected. Licensed manufacturers of blood and blood components, including Source Plasma; unlicensed registered blood establishments; and transfusion services who had control over the product when a deviation or unexpected event occurred are also required to submit BPD reports (21 CFR 606.171), if the safety, purity, or potency of a distributed product may be affected. In addition, manufacturers of nonreproductive Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) regulated by FDA solely under section 361 of the Public Health Service Act and 21 CFR Part 1271 are required to submit deviation reports [21 CFR 1271.350(b)] involving distributed products, if the deviation or unexpected event is related to a Core Current Good Tissue Practice requirement [21 CFR 1271.150(b)] and related to the prevention of communicable disease transmission or HCT/P contamination. Detailed information concerning deviation reporting, including guidance documents on BPD reporting for blood and plasma establishments (Ref. 1) and licensed manufacturers of biological products other than blood and blood components (Ref. 2), is available at <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/default.htm>.

This annual summary report provides an overview of the reports we received during the fiscal year, including detailed information regarding the number and types of deviation reports received. We provide combined data received over the last three fiscal years in an effort to compare data and highlight changes. Throughout the analysis, we report numbers from past reports, calculate changes, or consider aggregate counts from multiple BPD codes. These data may or may not be included in accompanying tables. Detailed counts for all BPD codes can be found in the attachments and past summary reports are available at <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/BiologicalProductDeviations/ucm129757.htm>.

Unfortunately, our system does not collect the necessary denominator data to calculate genuine rates when evaluating possible trends. Some perspective is gained by knowing that in calendar 2008, an estimated 17.3 million whole blood or red blood cell products plus 9.6 million other products (platelets, plasma, and cryoprecipitate) were collected and there were 22.6 million transfusions in the United States.¹ In addition, there were 19.8 million source plasma donations in 2010 and 23.6 million source plasma donations in 2011 made in the U.S.²

1 Report of the US Department of Health and Human Services. The 2009 national blood collection and utilization survey report. Washington, DC: US Department of Health and Human Services, Office of the Assistant Secretary of Health, 2011.

2 Plasma Protein Therapeutics Association at http://www.pptaglobal.org/UserFiles/file/Data/Collections_1999-2011_WEB.pdf

During fiscal year 2012 (hereafter FY12), October 1, 2011 through September 30, 2012, CBER's Office of Compliance and Biologics Quality/Division of Inspections and Surveillance entered 55,842 deviation reports into the BPD database (See Table 1):

- We received more than 55,842 reports, but this summary does not capture data for reports that did not meet the reporting threshold. We notified the reporter when a report was not required.
 - There was a 7% (3,852 reports) increase in the number of reports we received in FY12 compared to FY11 (See Table 2).
 - Blood and plasma establishments submitted 3,866 more reports in FY12 (See Table 2).
 - Licensed blood establishments submitted 270 more reports in FY12.
 - Unlicensed registered blood establishments submitted 57 fewer reports in FY12.
 - Transfusion services submitted 89 more reports in FY12.
 - Licensed plasma establishments submitted 3,564 more reports in FY12.
 - Manufacturers of licensed biological products other than blood and blood components submitted 17 fewer reports in FY12 compared to FY11 (See Table 2).
 - Licensed in-vitro diagnostic manufacturers submitted 26 more reports in FY12.
 - Blood derivative manufacturers submitted 18 more reports in FY12.
 - Licensed HCT/P manufacturers (351 HCT/P) submitted three more reports in FY12.
 - Allergenic manufacturers submitted 46 fewer reports in FY12.
 - Vaccine manufacturers submitted 18 fewer reports in FY12.
 - The number of reports we received from 361 HCT/P manufacturers in FY12 was similar to the reports we received in FY11 (See Table 2).
 - Cellular HCT/P manufacturers submitted 21 fewer reports in FY12.
 - Tissue HCT/P manufacturers submitted 24 more reports in FY12.
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- There were 48 more reporting establishments in FY12 (See Table 2).
 - Compared to FY11, there were 16 fewer licensed blood establishments, six more unlicensed blood establishments, 48 more transfusion services and three more licensed plasma establishments reporting in FY12.
 - Compared to FY11, there were two more vaccine manufacturers, two less blood derivative manufacturers, two less licensed in-vitro diagnostic manufacturers, one less allergenic manufacturer, and three more licensed HCT/P manufacturers (351 HCT/P) reporting in FY12.
 - Compared to FY11, there were seven more 361 HCT/P manufacturers reporting in FY12.

Since the number of reports continues to increase but the distribution of the types of events remain consistent, each firm responsible for reporting biological product deviations should use this information in evaluating their own deviation management program.

You may submit questions concerning this summary to:
FDA/Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
Division of Inspections and Surveillance (HFM-650)
1401 Rockville Pike, Suite 200 North
Rockville, Maryland 20852-1448

You may also contact us by email at bp_deviations@fda.hhs.gov, hctp_deviations@fda.hhs.gov, or sharon.ocallaghan@fda.hhs.gov (Sharon O'Callaghan) or by phone at 301-827-6220.

Total Deviation Reports FY12

Table 1

	Number Of Reporting Establishments	Total Reports Received	<i>Potential Recalls</i>	
Blood/Plasma Manufacturers				
Licensed Blood Establishments	221(113*)	25,024	583	2.3%
Unlicensed Blood Establishments ¹	420	3,961	26	0.7%
Transfusion Services ²	641	1,988	0	0.0%
Licensed Plasma Establishments	397(19*)	23,974	246	1.0%
<i>Sub-Total</i>	<i>1,679</i>	<i>54,947</i>	<i>855</i>	<i>1.6%</i>
Licensed Non-Blood Manufacturers				
Allergenic	6	136	3	2.2%
Blood Derivative	22(16*)	95	7	7.4%
In Vitro Diagnostic	12	128	4	3.1%
Vaccine	21(20*)	269	7	2.6%
351 HCT/P	4(1)	17	1	5.9%
<i>Sub-Total</i>	<i>65(55*)</i>	<i>645</i>	<i>22</i>	<i>3.4%</i>
361 HCT/P Manufacturers				
Cellular HCT/P	49	120	1	0.8%
Tissue HCT/P	45	130	42	32.3%
<i>Sub-Total</i>	<i>94</i>	<i>250</i>	<i>43</i>	<i>17.2%</i>
Total	1,838	55,842	920	1.6%

¹Unlicensed Blood Establishments – unlicensed blood establishments that perform manufacturing of blood and blood components are required to register with FDA

²Transfusion Services – blood banks that perform limited blood and blood component manufacturing (e.g. pooling, thawing, compatibility testing), may or may not register with FDA

*Number of license holders; one or more establishments operate under one biologics license.

Total Deviation Reports FY10 – FY12

Table 2

	Number Of Reporting Establishments			Total Reports Received			Potential Recalls		
	FY10	FY11	FY12	FY10	FY11	FY12	FY10	FY11	FY12
Blood/Plasma Manufacturers									
Licensed Blood Establishments	250(113*)	237(114*)	221(113*)	24,282	24,754	25,024	840	661	583
Unlicensed Blood Establishments ¹	425	414	420	3,850	4,018	3,961	27	31	26
Transfusion Services ²	545	593	641	1,760	1,899	1,988	0	0	0
Licensed Plasma Establishments	392(48*)	394(20*)	397(19*)	20,173	20,410	23,974	292	199	246
<i>Sub-Total</i>	<i>1,612</i>	<i>1,638</i>	<i>1,679</i>	<i>50,065</i>	<i>51,081</i>	<i>54,947</i>	<i>1,159</i>	<i>891</i>	<i>855</i>
Licensed Non-Blood Manufacturers									
Allergenic	7	7	6	197	182	136	4	1	3
Blood Derivative	23(16*)	24(17*)	22(16*)	99	77	95	0	7	7
In Vitro Diagnostic	14	14	12	117	102	128	12	6	4
Vaccine	17	19	21(20*)	242	287	269	8	4	7
351 HCT/P	2	1	4(1*)	6	14	17	0	5	1
<i>Sub-Total</i>	<i>63</i>	<i>65</i>	<i>65(55*)</i>	<i>661</i>	<i>662</i>	<i>645</i>	<i>24</i>	<i>23</i>	<i>22</i>
361 HCT/P Manufacturers									
Cellular HCT/P	43	49	49	160	141	120	1	0	1
Tissue HCT/P	32	38	45	126	106	130	28	14	42
<i>Sub-Total</i>	<i>75</i>	<i>87</i>	<i>94</i>	<i>286</i>	<i>247</i>	<i>250</i>	<i>29</i>	<i>14</i>	<i>43</i>
Total	1,750	1,790	1,838	51,012	51,990	55,842	1,212	928	920

¹Unlicensed Blood Establishments – unlicensed blood establishments that perform manufacturing of blood and blood components are required to register with FDA

²Transfusion Services – blood banks that perform limited blood and blood component manufacturing (e.g. pooling, thawing, compatibility testing), may or may not register with FDA

*Number of license holders; one or more establishments operate under one biologics license.

Blood & Plasma BPD Reports by Manufacturing System FY10 – FY12

Table 3

Manufacturing System	FY10		FY11		FY12	
Donor Suitability	39,222	78.3%	40,063	78.4%	43,540	79.2%
<i>Post Donation Information</i>	36,267	72.4%	36,547	71.5%	39,778	72.4%
<i>Donor Screening</i>	2,758	5.5%	2,796	5.5%	3,109	5.7%
<i>Donor Deferral</i>	197	0.4%	719	1.4%	653	1.2%
QC & Distribution	4,289	8.6%	4,183	8.2%	4,258	7.7%
Miscellaneous	2,074	4.1%	2,536	5.0%	2,934	5.3%
Labeling	2,118	4.2%	2,122	4.2%	2,050	3.7%
Laboratory Testing	1,019	2.0%	1,059	2.1%	987	1.8%
<i>Routine Testing</i>	1,007	2.0%	1,046	2.0%	977	1.8%
<i>Viral Testing</i>	12	0.0%	13	0.0%	9	0.0%
Collection	1,019	2.0%	839	1.6%	906	1.6%
Component Preparation	324	0.6%	280	0.5%	273	0.5%
Total	50,065	100%	51,081	100%	54,947	100%

Licensed Non-Blood Deviation Reports by Manufacturing System FY10 – FY12

Table 4

Manufacturing System	Allergenic			Blood Derivative			In Vitro Diagnostic		
	FY10	FY11	FY12	FY10	FY11	FY12	FY10	FY11	FY12
Product Specifications	179	169	112	25	27	32	52	37	49
Quality Control & Distribution	2	1	0	9	9	11	31	34	51
Labeling	7	6	22	4	10	9	14	13	5
Process Controls	9	3	0	35	16	25	6	12	13
Testing	0	3	1	9	5	7	9	3	5
Incoming Material	0	0	1	15	10	11	4	2	3
Miscellaneous	0	0	0	2	0	0	1	1	2
Total	197	182	136	99	77	95	117	102	128

Table 4 (continued)

Manufacturing System	Vaccine			351 HCT/P			Total		
	FY10	FY11	FY12	FY10	FY11	FY12	FY10	FY11	FY12
Product Specifications	91	114	126	2	5	8	349	352	327
Quality Control & Distribution	93	85	45	1	0	0	136	129	107
Labeling	16	21	22	1	4	6	42	54	64
Process Controls	13	22	22	0	1	1	63	54	61
Testing	14	22	18	0	1	2	32	34	33
Incoming Material	11	11	16	2	3	0	32	26	31
Miscellaneous	4	12	20	0	0	0	7	13	22
Total	242	287	269	6	14	17	661	662	645

361 HCT/P Deviation Reports by Manufacturing System FY10 – FY12

Table 5

Manufacturing System	Cellular HCT/Ps			Tissue HCT/Ps			Total		
	FY10	FY11	FY12	FY10	FY11	FY12	FY10	FY11	FY12
Processing & Processing Controls	64	74	59	17	8	18	81	82	77
Receipt, Pre-Distrib., Shipment & Distrib.	53	52	46	4	5	3	57	57	49
Donor Screening	1	1	1	20	17	39	21	18	40
Donor Eligibility	3	0	0	23	26	37	26	26	37
Donor Testing	27	1	1	56	41	17	83	42	18
Supplies and Reagents	0	10	8	4	2	4	4	12	12
Labeling Controls	1	1	1	1	5	6	2	6	7
Recovery	9	1	1	0	2	3	9	3	4
Environmental Control	1	0	1	1	0	2	2	0	3
Storage	1	1	1	0	0	1	1	1	2
Equipment	0	0	1	0	0	0	0	0	1
Total	160	141	120	126	106	130	286	247	250

II. BPD Reports Submitted by Blood and Plasma Establishments:

General Overview

Blood and plasma establishments submitted 3,866 more reports in FY12 than in the previous fiscal year (FY11-51,081).

- Licensed blood establishments submitted 270 more reports in FY12 (FY11-24,754).
 - The number of reports involving donor screening increased from 2,171 in FY11 to 2,318 in FY12.
 - There were 171 more reports in FY12 in which the incorrect donor identification was used during deferral search (FY11-1,414).
 - There were 94 more reports in FY12 involving miscellaneous deviations or unexpected events (FY11-837, FY12-931).
 - The number of reports involving donors who subsequently tested confirmed positive for a viral marker increased from 820 in FY11 to 914 in FY12. Specifically, the number of reports involving donors who tested confirmed positive for Hepatitis C increased from 416 in FY11 to 502 in FY12.
 - The number of reports in which a donor was implicated in or could not be ruled out of a transfusion transmitted disease was the same as the previous year (17 reports in FY11 and FY12).
 - The number of reports involving blood collection increased from 769 in FY11 to 846 in FY12.
 - The number of reports involving clotted units increased from 599 in FY11 to 640 in FY12.
 - The number of reports involving sterility compromised increased from 75 in FY11 to 104 in FY12, specifically involving bacterial contamination (FY11-39, FY12-61).
 - The number of reports involving post donation information was similar to the reports we received in FY11 (FY11-18,111, FY12-18,170).
 - There were 550 more reports involving a male donor who had sex with another male (FY11-441, FY12-991).
 - There were 254 more reports involving a donor who traveled to a malarial endemic area (FY11-6,483, FY12-6,737).
 - There were 231 fewer reports involving a donor who traveled to a vCJD risk area (FY11-3,093, FY12-2,862).
 - There were 218 fewer reports involving a donor who reported a post donation illness (FY11-1,084, FY12-866).
- Unlicensed registered blood establishments submitted 57 fewer reports in FY12 (FY11-4,018).
 - The number of reports involving quality control and distribution decreased from 1,943 in FY11 to 1,870 in FY12.

- The number of reports involving distribution procedures not performed in accordance with the blood bank transfusion service's specifications decreased from 1,501 in FY11 to 1,414 in FY12.
 - The number of reports involving routine testing decreased from 420 in FY11 to 365 in FY12.
 - The number of reports involving post donation information increased from 365 in FY11 to 462 in FY12. Most frequently, these events related to donors who traveled to risk areas (FY11-209, FY12-254).
- Transfusion services submitted 89 more reports in FY12 (FY11-1,899).
 - Unregistered transfusion services typically report few BPDs (67% of those reporting in FY12 submitted 1 or 2 reports) and may file no reports in a given year. Only 13% of the transfusion services submitted more than five reports during FY12.
 - The number of reports involving quality control and distribution increased from 1,019 in FY11 to 1,177 in FY12.
 - The number of reports involving labeling decreased from 518 in FY11 to 446 in FY12.
- Licensed plasma establishments submitted 3,564 more reports in FY12 (FY11-20,410).
 - The number of reports involving post donation information increased 17% (FY11-18,071, FY12-2,146).

There was an increase in the number of reports involving a donor who:

- Had a history of tattoo and/or piercing (FY11-12,393, FY12-14,587)
- Had a history of incarceration (FY11-946, FY12-1,010)
- Had a history of IV drug use (FY11-251, FY12-319)
- Was found reactive for a viral marker at another facility (FY11-334, FY12-529)
- Had a sex partner that was reactive for HIV, Hepatitis B, or Hepatitis C (FY11-402, FY12-520)
 - ❖ HIV: FY11-86, FY12-132
 - ❖ HBV: FY11-66, FY12-94
 - ❖ HCV: FY11-247, FY12-283
- The number of reports in which a donor had non-sexual exposure to someone with HIV, Hepatitis B, or Hepatitis C were similar to the reports we received in FY11 (FY11-942, FY12-956)
 - ❖ HCV: FY11-756, FY12-787
 - ❖ HIV: FY11-14, FY12-10
 - ❖ HBV: FY11-162, FY12-152

There was a decrease in the number of reports involving a donor who:

- Had traveled to a vCJD risk area (FY11-298, FY12-238)
- Had a positive drug screen (FY11-321, FY12-24)

- The number of reports involving distributed products collected from a donor who subsequently tested confirmed positive for a viral marker increased 18% (FY11-1,687, FY12-1,988).
 - The number of reports in which a donor subsequently tested confirmed positive for HCV increased 26% (FY11-1,007, FY12-1,270).
- The number of reports involving donor screening increased 35% from 541 in FY11 to 732 in FY12.
 - The number of reports involving incomplete or incorrect donor records increased from 177 in FY11 to 318 in FY12. 66% of the reports involved donor screening deviations, in which all of the donor history questions were not asked as required.
 - The number of reports involving not performing or incorrectly performing deferral screening increased from 26 in FY11 to 137 in FY12. 88% of the reports involved donors who were previously identified as illiterate and were improperly screened (i.e., self-administered questionnaire allowed instead of screening performed by center personnel).

Total BPDRs by Manufacturing System Blood and Plasma Establishments

Table 6

Manufacturing System	Licensed Blood Establishments	Unlicensed Blood Establishments	Transfusion Services	Licensed Plasma Establishments	Total	
DS-Post Donation Information	18,170	462	NA	21,146	39,778	72.4%
QC & Distribution	1,119	1,870	1,177	92	4,258	7.7%
DS-Donor Screening	2,318	59	NA	732	3,109	5.7%
Miscellaneous	931	15	NA	1,988	2,934	5.3%
Labeling	536	1,063	446	5	2,050	3.7%
LT-Routine Testing	253	365	359	0	977	1.8%
Blood Collection	846	59	NA	1	906	1.6%
DS-Donor Deferral	642	2	NA	9	653	1.2%
Component Preparation	202	65	6	0	273	0.5%
LT-Viral Testing	7	1	NA	1	9	0.0%
Total	25,024	3,961	1,988	23,974	54,947	100%

DS-Donor Suitability

LT-Laboratory Testing

NA-Not applicable: manufacturing not performed in transfusion service

Post Donation Information

Post donation information (PDI) continues to be the most frequently reported event associated with the manufacturing of blood and plasma products (72% of deviation reports) (See Table 6). The number of reports blood and plasma establishments submitted involving post donation information increased 9% from the previous fiscal year (FY11-36,548, FY12-39,778)

- Blood establishments submitted 59 more reports involving post donation information in FY12 compared to FY11. They submitted 287 more reports involving a donor who traveled to a malarial risk area, 219 fewer reports involving a donor who traveled to a vCJD risk area and 280 fewer reports involving post donation illness.
- Licensed plasma establishments submitted 3,074 more reports involving post donation information, which is an increase of 17%, in FY12 compared to FY11. They submitted 2,194 more reports involving donors who had a history of tattoo and/or piercing.

Table 7 illustrates the major differences in post donation information reports from FY10 to FY12. It does not include all post donation information reports.

PDI Reports Submitted by Blood and Plasma Establishments

Table 7

Blood Establishments	FY10	FY11	FY12
Post Donation Information (PD) – <i>total</i>	18,229	18,476	18,632
Donor had a history of travel to malarial risk area	6,553	6,625	6,912
Donor had a history of travel to vCJD risk area	3,296	3,160	2,941
Donor received tattoo and/or piercing	1,466	1,577	1,566
Donor had history of male to male sex	810	924	1,016
Post donation illness	1,030	1,098	818

Licensed Plasma Establishments	FY10	FY11	FY12
Post Donation Information (PD) – <i>total</i>	18,038	18,072	21,146
Donor received tattoo and/or piercing	13,155	12,393	14,587
Donor had a history of incarceration	1,126	946	1,010
Donor had a history of non-sexual exposure to Hepatitis C	332	756	787

Miscellaneous

The number of reports blood and plasma establishments submitted in which they distributed a unit that was collected from a donor who subsequently tested confirmed positive for a viral marker (on a later donation) increased 16% from the previous fiscal year (FY11-2,517, FY12-2,915).

- The number of these reports submitted by blood establishments increased 12% (FY11-830, FY12-927) from the previous fiscal year.
- The number of these reports submitted by licensed plasma establishments increased 18% from the previous fiscal year (FY11-1,687, FY12-1,988).

Table 8 illustrates the number of reports related to units collected from donors who subsequently tested confirmed positive for selected viral markers (lookback).

Viral Marker Lookback Reports Submitted by Blood and Plasma Establishments

Table 8

Blood Establishments	FY08	FY09	FY10	FY11	FY12
Lookback; Subsequent unit confirmed positive (MI02) - <i>total</i>	852	874	687	830	927
HCV (MI0204)	405	527	377	421	506
HIV (MI0202)	152	133	167	183	180
HBV (MI0203)	140	127	93	157	140

Licensed Plasma Establishments	FY08	FY09	FY10	FY11	FY12
Lookback; Subsequent unit confirmed positive (MI02) - <i>total</i>	1,038	1,363	1,362	1,687	1,988
HCV (MI0204)	579	814	725	1,007	1,270
HBV (MI0203)	324	401	461	482	472
HIV (MI0202)	129	146	172	192	243

A. Most Frequent BPD Reports Submitted by Licensed Blood Establishments³

Of the 25,024 reports submitted by licensed blood establishments, 18,170 (72.6%) reports involved **post donation information**.

- The number of these reports was similar to the reports we received in FY11 (FY11-18,111).
- The number of reports in which a donor or third party provided subsequent information related to high risk behavior or history increased 1% (FY11-16,811).
 - The number of reports in which a donor or third party provided subsequent information regarding travel to a malaria risk area increased 4% (FY11-6,483).
 - The number of reports in which a donor or third party provided subsequent information regarding travel to a vCJD risk area decreased 7% (FY11-3,093).
- The number of reports in which a donor or third party provided subsequent information related to a post donation illness decreased 20% (FY11-1,084).

Most Frequent BPD Reports - Post Donation Information From *Licensed Blood Establishments*

Table 9

POST DONATION INFORMATION	18,170	# Reports	% of Total (PD)
<i>Behavior/History</i>		17,042	93.8%
Travel to malaria endemic area/history of malaria		6,737	37.1%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) – travel		2,862	15.8%
Donor received tattoo and/or piercing		1,540	8.5%
Male donor had sex with another man		991	5.5%
<i>Illness</i>		866	4.8%
Post donation illness (not hepatitis, HIV, HTLV-I, STD, cancer, or cold/flu related)		801	4.4%
<i>Fever/diarrhea</i>		388	2.1%
<i>Infection</i>		283	1.6%
Post donation diagnosis or symptoms of HIV		19	0.1%
Post donation diagnosis or symptoms of sexually transmitted disease		15	0.1%
<i>Testing *</i>		220	1.2%
Tested reactive for HIV prior to donation		45	0.2%
Tested reactive for Hepatitis C post donation		38	0.2%
Tested reactive for HIV post donation		29	0.2%
Tested reactive for Hepatitis C prior to donation		26	0.1%
<i>Not specifically related to high risk behavior</i>		42	0.2%
Donor does not want their blood used		22	0.1%
Donated to be tested or called back for test results		18	0.1%

*Includes: tested positive for viral marker either prior to or post donation at another location

³ Licensed blood establishments do not include Source Plasma establishments, for the purpose of this summary.

Of the 25,024 reports submitted by licensed blood establishments, 2,318 (9.3%) reports involved **donor screening** deviations or unexpected events.

- The number of these reports increased 7% (FY11-2,171).
- The number of reports in which the incorrect identification was used during the deferral search increased 12% (FY11-1,414).
- The number of reports in which the donor gave a history that warranted deferral or follow up and was not deferred was similar to the reports we received in FY11 (FY11-279).
- The number of reports in which the donor record was incomplete or incorrect was similar to the reports we received in FY11 (FY11-409).

Most Frequent BPD Reports – Donor Screening From *Licensed Blood Establishments*

Table 10

DONOR SCREENING (DS)	2,318	# Reports	% of Total (DS)
<i>Incorrect ID used during deferral search</i>		1,585	68.4%
Donor not previously deferred		1,502	64.8%
Donor previously deferred due to history		57	2.5%
Donor previously deferred due to testing		26	1.1%
<i>Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked</i>		252	10.9%
Travel to malaria endemic area/history of malaria		118	5.1%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel		54	2.3%
<i>Donor record incomplete or incorrect</i>		418	18.0%
Donor history questions		345	14.9%
<i>Incorrect gender specific questions asked</i>		191	8.2%
Donor identification		31	1.3%
Donor signature missing		18	0.8%
<i>Donor did not meet acceptance criteria</i>		44	1.9%
Hemoglobin or Hematocrit unacceptable or not documented or testing was performed incorrectly		17	0.7%
Temperature unacceptable or not documented		9	0.4%
<i>Deferral screening not done or incorrectly performed</i>		18	0.8%
Donor previously deferred due to history		15	0.6%
Donor previously deferred due to testing		3	0.1%
Donor not previously deferred		0	0.0%

Of the 25,024 reports submitted by licensed blood establishments, 1,119 (4.5%) reports involved **quality control and distribution** deviations or unexpected events.

- The number of these reports decreased 3% (FY11-1,149).
- The number of reports involving the distribution of a product that did not meet specifications was similar to the reports we received in FY11 (FY11-778).
 - The number of reports involving the release of a product with unacceptable, undocumented, or incomplete product QC decreased 11% (FY11-539). The number of reports related to bacterial detection testing decreased 25% (FY11-368).
- The number of reports involving shipping and storage were similar to the reports we received in FY11 (FY11-182)

Most Frequent BPD Reports –Quality Control & Distribution
From Licensed Blood Establishments

Table 11

QC & DISTRIBUTION (QC)	1,119	# Reports	% of Total (QC)
<i>Distribution of product that did not meet specifications</i>		766	68.5%
Product QC unacceptable, not performed, not documented, or incomplete		479	42.8%
<i>Bacterial detection testing</i>		276	24.7%
<i>White Blood Cell count</i>		73	6.5%
Product in which instrument QC or validation was unacceptable, incomplete, not performed or documented		88	7.9%
Product identified as unsuitable due to a collection deviation or unexpected event		44	3.9%
Product in which specification other than QC was not met		38	3.4%
Product identified as unsuitable due to a donor screening deviation or unexpected event		33	2.9%
<i>Shipping and storage</i>		180	16.1%
Product not packaged in accordance with specifications or no documentation that product was packed appropriately		53	4.7%
No documentation that product was shipped or stored at appropriate temperature		32	2.9%
Product arrived at consignee at unacceptable temperature		29	2.6%
<i>Distribution procedures not performed in accordance with blood bank transfusion service's specifications</i>		89	8.0%
Product not irradiated as required		23	2.1%
Product not documented or incorrectly documented as issued in the computer		17	1.5%
Improper product selected for patient		14	1.3%
<i>Testing not performed, incompletely performed, or not documented</i>		51	4.6%
Antibody screen or identification		14	1.3%
Chagas		9	0.8%
Antigen screen		8	0.7%
<i>Failure to quarantine unit due to medical history:</i>		21	1.9%
Post donation illness		12	1.1%
<i>Positive testing</i>		12	1.1%

Of the 25,024 reports submitted by licensed blood establishments, 931 (3.7%) reports involved **miscellaneous** deviations or unexpected events.

- The number of these reports increased 11% (FY11-837).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for a viral marker increased 11% (FY11-820).
 - The number of reports in which a donor subsequently tested confirmed positive for HCV increased 21% (FY11-416).
 - The number of reports in which a donor subsequently tested confirmed positive for HIV was similar to the reports we received in FY11 (FY11-182).
 - The number of reports in which a donor subsequently tested confirmed positive for HBV decreased from 154 in FY11 to 137 in FY12.
- The number of reports in which a donor was either implicated in or not ruled out of a transfusion associated disease was the same as the reports we received in FY11. There were six more reports received in FY12 involving Babesia (FY11-8).

Most Frequent BPD Reports - Miscellaneous
From *Licensed Blood Establishments*

Table 12

MISCELLANEOUS (MI)	931	# Reports	% of Total (MI)
<i>Lookback; subsequent unit tested confirmed positive for:</i>		914	98.2%
HCV		502	53.9%
HIV		178	19.1%
HBV		137	14.7%
<i>2x Anti-HBc positive</i>		65	7.0%
Chagas		35	3.8%
West Nile Virus		31	3.3%
<i>Donor implicated in transfusion associated disease</i>		17	1.8%
Babesia		14	1.5%

Of the 25,024 reports submitted by licensed blood establishments, 846 (3.4%) reports involved **blood collection** deviations or unexpected events.

- The number of these reports increased 10% (FY11-769).
- The number of reports involving the collection process increased 6% (FY11-676).
 - The number of reports involving clotted units increased 7% (FY11-599).
- The number of reports in which the sterility of a product may have been compromised increased from 75 in FY11 to 104 in FY12.
 - The number of reports involving bacterial contamination increased from 39 in FY11 to 61 in FY12.

Most Frequent BPD Reports – Blood Collection
From *Licensed Blood Establishments*

Table 13

BLOOD COLLECTION (BC)	846	#Reports	% of Total (BC)
<i>Collection process</i>		718	84.9%
Product contained clots, not discovered prior to distribution		640	75.7%
Apheresis collection process		26	3.1%
Product hemolyzed, not discovered prior to distribution		23	2.7%
<i>Sterility compromised</i>		104	12.3%
Bacterial contamination		61	7.2%
Arm prep not performed or performed inappropriately		25	3.0%
Air contamination		17	2.0%
<i>Collection bag</i>		17	2.0%
Potential collection set defect		14	1.7%

B. Most Frequent BPD Reports Submitted by Unlicensed Registered Blood Establishments

Of the 3,961 reports submitted by unlicensed registered blood establishments, 1,870 (47.2%) involved **quality control and distribution** deviations or unexpected events.

- The number of these reports decreased 4% (FY11-1,943).
- The number of reports involving distribution procedures not performed in accordance with the blood bank transfusion service's specifications decreased 6% (FY11-1,501).
 - The number of reports involving the release of a product that was not documented or incorrectly documented as issued in the computer, which was the only method of documenting the visual and clerical checks at the time of distribution, decreased 10% (FY11-738).
 - The number of reports involving the improper product or product with the improper ABO and/or Rh issued to a patient increased from 203 in FY11 to 223 in FY12.
- In FY12, we received 16 more reports involving the distribution of a product that did not meet specifications (FY11-139).

Most Frequent BPD Reports - Quality Control & Distribution From Unlicensed Registered Blood Establishments

Table 14

QC & DISTRIBUTION (QC)	1,870	# Reports	% of Total (QC)
<i>Distribution procedures not performed in accordance with blood bank transfusion service's specifications</i>		1,416	75.7%
Product not documented or incorrectly documented as issued in the computer		661	35.3%
Product not irradiated as required		204	10.9%
Improper product selected for patient		138	7.4%
Improper ABO or Rh type selected for patient		85	4.5%
Procedure for issuing not performed or documented in accordance with specifications		77	4.1%
<i>Testing not performed, incompletely performed, or not documented</i>		242	12.9%
ABO and/or Rh		69	3.7%
Antibody screen or identification		57	3.0%
Antigen screen		47	2.5%
Compatibility		38	2.0%
<i>Distribution of product that did not meet specifications</i>		155	8.3%
Product QC unacceptable, not performed, not documented or incomplete		61	3.3%
<i>Bacterial detection testing</i>		37	2.0%
Product in which instrument QC or validation unacceptable, incomplete or not documented		46	2.5%
Outdated product		23	1.2%
<i>Shipping and storage</i>		50	2.7%
No documentation that product was shipped or stored at appropriate temperature		20	1.1%
Stored at incorrect temperature		12	0.6%

Of the 3,961 reports submitted by unlicensed registered blood establishments, 1,063 (26.8%) involved **labeling** deviations or unexpected events.

- The number of these reports was similar to the reports we received in FY11 (FY11-1,037).
- In FY12, we received 69 more reports involving the crossmatch tag or tie tag labeled with incorrect or missing information (FY11-519).
- In FY12, we received 5 more reports involving the unit labeled with incorrect or missing information (FY11-271).
- In FY12, we received 48 fewer reports involving the transfusion record labeled with incorrect or missing information (FY11-247).

Most Frequent BPD Reports - Labeling
From Unlicensed Registered Blood Establishments

Table 15

LABELING (LA)	1,063	#Reports	% of Total (LA)
<i>Crossmatch tag or tie tag labels incorrect or missing information</i>		588	55.3%
Recipient identification incorrect or missing		164	15.4%
Crossmatch tag switched, both units intended for the same patient		159	15.0%
Unit, lot, or pool number incorrect or missing		94	8.8%
<i>Labels applied to blood unit or product incorrect or missing information</i>		276	26.0%
Extended expiration date or time		112	10.5%
Irradiation status incorrect or missing		49	4.6%
Product type or code incorrect or missing		34	3.2%
Donor/unit number or lot number incorrect or missing		17	1.6%
<i>Transfusion record (crossmatch slip) incorrect or missing information</i>		199	18.7%
Transfusion record switched, both units intended for the same patient		69	6.5%
Recipient identification incorrect or missing		44	4.1%
Unit, lot, or pool number incorrect or missing		27	2.5%

Of the 3,961 reports submitted by unlicensed registered blood establishments, 462 (11.7%) reports involved **post donation information**.

- The number of these reports increased 27% (FY11-365).
- The number of reports in which a donor or third party provided subsequent information related to high risk behavior or history increased 24% (FY11-347).
 - The number of reports in which a donor or third party provided subsequent information regarding travel to a malarial risk area increased from 142 in FY11 to 175 in FY12.
 - The number of reports in which a donor or third party provided subsequent information regarding travel to a vCJD risk area increased from 67 in FY11 to 79 in FY12.
- The number of reports in which a donor or third party provided subsequent information related to post donation illness increased from 14 in FY11 to 20 in FY12.

Most Frequent BPD Reports - Post Donation Information
From *Unlicensed Registered Blood Establishments*

Table 16

POST DONATION INFORMATION (PD)	462	# Reports	% of Total (PD)
<i>Behavior/History</i>		429	92.9%
Travel to malaria endemic area/history of malaria		175	37.9%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) – travel		79	17.1%
Donor received tattoo and/or piercing		26	5.6%
Male donor had sex with another man		25	5.4%
<i>Illness</i>		20	4.3%
<i>Testing*</i>		7	1.5%

*Includes: tested positive for viral marker either prior to or post donation at another location

Of the 3,961 reports submitted by unlicensed registered blood establishments, 365 (9.2%) reports involved **routine testing** deviations or unexpected events.

- The number of these reports decreased 13% (FY11-420).
- The number of reports involving testing performed, interpreted or documented incorrectly was similar to the reports we received in FY11 (FY11-230).
- The number of reports involving sample identification decreased from 136 in FY11 to 78 in FY12.
- The number of reports involving unacceptable reagent QC or the use of expired reagents was similar to the reports we received in FY11 (FY11-54).

Most Frequent BPD Reports - Routine Testing
From Unlicensed Registered Blood Establishments

Table 17

ROUTINE TESTING (RT)	365	# Reports	% of Total (RT)
Testing performed, interpreted, or documented incorrectly		229	62.7%
Compatibility		76	20.8%
Antibody screening or identification		63	17.3%
ABO and/or Rh		39	10.7%
Antigen typing		32	8.8%
Sample (used for testing) identification		78	21.4%
Sample used for testing was incorrectly or incompletely labeled		55	15.1%
Unsuitable sample used for testing (e.g., too old)		19	5.2%
Testing performed using reagents in which QC was unacceptable, not performed, not documented, or expired reagents were used		58	15.9%
Antigen typing		14	3.8%
Antibody screening or identification		11	3.0%
ABO and/or Rh		11	3.0%

C. Most Frequent BPD Reports Submitted by Transfusion Services

Of the 1,988 reports submitted by transfusion services, 1,177 (59.2%) reports involved **quality control and distribution** deviations or unexpected events.

- The number of these reports increased 16% (FY11-1,019).
- The number of reports involving distribution procedures not performed in accordance with the blood bank transfusion service's specifications increased 22% (FY11-689).
 - The number of reports involving the release of a product that was not documented or incorrectly documented as issued in the computer, which was the only method of documenting the visual and clerical checks at the time of distribution, increased 20% (FY11-381).
 - The number of reports involving the distribution of a product that was not irradiated as requested increased from 77 in FY11 to 101 in FY12
 - The number of reports involving the improper product or product with the improper ABO and/or Rh issued to a patient increased from 68 in FY11 to 103 in FY12.

Most Frequent BPD Reports - Quality Control & Distribution From Transfusion Services

Table 18

QC & DISTRIBUTION (QC)	1,177	# Reports	% of Total (QC)
<i>Distribution procedures not performed in accordance with blood bank transfusion service's specifications</i>		838	71.2%
Product not documented or incorrectly documented as issued in the computer		458	38.9%
Product not irradiated as required		101	8.6%
Improper product selected for patient		52	4.4%
Improper ABO or Rh type selected for patient		51	4.3%
Procedure for issuing not performed or documented in accordance with specifications		46	3.9%
<i>Testing not performed, incompletely performed, or not documented</i>		249	21.2%
ABO and/or Rh		69	5.9%
Antibody screen or identification		61	5.2%
Antigen screen		57	4.8%
<i>Distribution of product that did not meet specifications</i>		44	3.7%
Outdated product		24	2.0%
<i>Shipping and storage</i>		46	3.9%
No documentation that product was shipped or stored at appropriate temperature		20	1.7%
Stored at incorrect temperature		11	0.9%
Temperature not recorded or unacceptable upon return, unit redistributed		9	0.8%

Of the 1,988 reports submitted by transfusion services, 446 (22.4%) reports involved **labeling** deviations or unexpected events.

- The number of these reports decreased 14% (FY11-518).
- The number of reports involving the labeling of the crossmatch or tie tag increased from 297 in FY11 to 307 in FY12.
- The number of reports involving the labeling of the transfusion record decreased 46% (FY11-159).
- The number of reports involving the labeling of the product decreased from 62 in FY11 to 48 in FY12.

Most Frequent BPD Reports - Labeling
From Transfusion Services

Table 19

LABELING (LA)	446	# Reports	% of Total (LA)
<i>Crossmatch tag or tie tag labels incorrect or missing information</i>		307	68.8%
Recipient identification incorrect or missing		78	17.5%
Unit, lot, or pool number incorrect or missing		65	14.6%
Crossmatch tag switched, both units intended for the same patient		63	14.1%
Product type or code incorrect or missing		30	6.7%
Crossmatch tag or tie tag missing or attached to incorrect unit		21	4.7%
<i>Transfusion record (crossmatch slip) incorrect or missing information</i>		86	19.3%
Transfusion records switched, both units intended for the same patient		23	5.2%
Unit, lot, or pool number incorrect or missing		17	3.8%
Recipient identification incorrect or missing		14	3.1%
Product type or code incorrect or missing		10	2.2%
<i>Labels applied to blood unit or product incorrect or missing information</i>		48	10.8%
Expiration date or time extended or missing		32	7.2%
Product type/code and expiration date incorrect or missing		10	2.2%
CMV status incorrect or missing		3	0.7%

Of the 1,988 reports submitted by transfusion services, 359 (18.1%) reports involved **routine testing** deviations or unexpected events.

- The number of these reports was similar to the reports we received in FY11 (FY11-353).
- The number of reports involving testing performed, interpreted or documented incorrectly was similar to the reports we received in FY11 (FY11-228).
- The number of reports involving unacceptable reagent QC or the use of expired reagents was similar to the reports we received in FY11 (FY11-66).
- The number of reports involving sample identification was similar to the reports we received in FY11 (FY11-59).

Most Frequent BPD Reports - Routine Testing From Transfusion Services

Table 20

ROUTINE TESTING (RT)	359	# Reports	% of Total (RT)
<i>Testing performed, interpreted, or documented incorrectly</i>	232		64.7%
Compatibility	92		25.6%
Antibody screening or identification	73		20.3%
Antigen typing	28		7.8%
ABO and/or Rh typing	24		6.7%
<i>Testing performed using reagents in which QC was unacceptable, not performed, not documented, or expired reagents were used</i>	65		18.1%
Antibody screening or identification	18		5.0%
Antigen typing	15		4.2%
Multiple testing	14		3.9%
<i>Sample (used for testing) identification</i>	61		16.9%
Sample used for testing was incorrectly or incompletely labeled	49		13.6%
Unsuitable sample used for testing	9		2.5%
Incorrect sample tested	3		0.8%

D. Most Frequent BPD Reports Submitted by Licensed Plasma Establishments

Of the 23,974 reports submitted by licensed plasma establishments, 21,146 (88.2%) involved **post donation information**.

- The number of these reports increased 17% (FY11-18,071).
- The number of reports in which a donor or third party provided subsequent information related to high risk behavior or history increased 16% (FY11-17,613).
 - The number of reports in which the donor had a history of a tattoo and/or piercing increased 18% (FY11-12,393).
 - The number of reports in which the donor had a history of incarceration increased from 946 in FY11 to 1,010 in FY12.
 - Although the number of reports in which the donor had non-sexual exposure to hepatitis (Hepatitis B or Hepatitis C) more than doubled from FY10 to FY11, the number of reports received in FY12 were similar to the previous fiscal year (FY10-390; FY11-918, FY12-939).
- The number of reports in which a donor or third party provided subsequent information related to testing by another facility increased 43% (FY11-438).
 - The number of reports in which the donor tested positive by another facility, but the specific testing was unknown, increased 58% (FY11-334).

Most Frequent BPD Reports - Post Donation Information From *Licensed Plasma Establishments*

Table 21

POST DONATION INFORMATION (PD)	21,146	# Reports	% of Total (PD)
<i>Behavior/History</i>		20,498	96.9%
Donor received tattoo and/or piercing		14,587	69.0%
Incarcerated		1,010	4.8%
Non-sexual exposure to Hepatitis C		787	3.7%
Other; unacceptable address, donor unreliable		554	2.6%
History of disease or surgery		529	2.5%
Donor received medication or antibiotics		390	1.8%
IV drug use		319	1.5%
Sex partner tested reactive for HCV		283	1.3%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) – travel		238	1.1%
<i>Testing*</i>		627	3.0%
Tested reactive at another center, specific testing unknown		529	2.5%
Tested reactive for HCV post donation		38	0.2%
Tested reactive for HIV post donation		23	0.1%
Tested reactive for HBV post donation		13	0.1%
<i>Illness</i>		16	0.1%

*Includes testing positive for viral marker prior to or post donation at another location

Of the 23,974 reports submitted by licensed plasma establishments, 1,988 (8.3%) reports involved **miscellaneous** deviations or unexpected events.

- The number of these reports increased 18% (FY11-1,687).
- The number of reports in which distributed products were collected from a donor who subsequently tested confirmed positive for HCV increased 26% (FY11-1,007).
- In FY12, we received 10 fewer reports in which distributed products were collected from a donor who subsequently tested confirmed positive for HBV (FY11-482).
- In FY12, we received 51 more reports in which distributed products were collected from a donor who subsequently tested confirmed positive for HIV (FY11-192).

Most Frequent BPD Reports - Miscellaneous
From *Licensed Plasma Establishments*

Table 22

MISCELLANEOUS (MI)	1,988	# Reports	% of Total (MI)
<i>Lookback; subsequent unit tested confirmed positive for:</i>	1,988		100%
HCV	1,270		63.9%
HBV	472		23.7%
HIV	243		12.2%

Of the 23,974 reports submitted by licensed plasma establishments, 732 (3.1%) reports involved **donor screening** deviations or unexpected events.

- The number of these reports increased 35% (FY11-541).
- The number of reports involving incomplete or incorrect donor records increased from 177 in FY11 to 318 in FY12. 66% of the reports involved donor screening deviations, in which all of the donor history questions were not asked as required.
- The number of reports involving donors who did not meet acceptance criteria were similar to reports we received in FY11 (FY11-205).
 - There were 34 fewer reports involving not performing or inadequately performing the medical review or physical (FY11-155).
 - There were 37 more reports involving the donor's temperature not documented or unacceptable (FY11-5).
- The number of reports involving not performing or incorrectly performing deferral screening increased from 26 in FY11 to 137 in FY12. 88% of the reports involved donors who were previously identified as illiterate and were improperly screened (i.e., self-administered questionnaire allowed instead of screening performed by center personnel).
- The number of reports in which the donor gave a history that warranted deferral or follow up and was not deferred decreased from 129 in FY11 to 63 in FY12.
 - The number of reports involving a donor who had a history of a tattoo and/or piercing decreased from 90 in FY11 to 34 in FY12.

Most Frequent BPD Reports - Donor Screening From *Licensed Plasma Establishments*

Table 23

DONOR SCREENING (DS)	732	# Reports	% of Total (DS)
<i>Donor record incomplete or incorrect</i>		318	43.4%
Donor history questions		250	34.2%
Donor identification		50	6.8%
Donor signature missing		15	2.0%
<i>Donor did not meet acceptance criteria</i>		211	28.8%
Medical review or physical not performed or inadequate		121	16.5%
Unacceptable address or no proof of address		48	6.6%
Temperature unacceptable or not documented		42	5.7%
<i>Deferral screening not done or incorrectly performed</i>		137	18.7%
Donor unreliable/illiterate		127	17.3%
<i>Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked</i>		63	8.6%
Donor received tattoo and/or piercing		34	4.6%
Donor received medication or antibiotics		7	1.0%
<i>Incorrect ID used during deferral search</i>		3	0.4%

III. BPD Reports Submitted by Manufacturers of Licensed Biological Products Other Than Blood and Blood Components (Licensed Non-Blood)

Licensed non-blood manufacturers submitted 17 fewer report in FY12 than in the previous fiscal year (FY11-662) (See Table 2).

- Vaccine manufacturers submitted 18 fewer reports (FY11-287).
 - The number of reports involving product specifications increased from 114 in FY11 to 126 in FY12.
 - The number of reports involving product not meeting specifications increased from 56 in FY11 to 79 in FY12, specifically related to appearance, which increased from 48 in FY11 to 70 in FY12.
 - The number of reports involving stability failures for potency was similar to the reports we received in FY11 (FY11-22, FY12-19).
 - The number of reports involving quality control and distribution decreased from 85 in FY11 to 45 in FY12.
 - The number of reports involving broken or cracked vials decreased from 76 in FY11 to 38 in FY12.
- Allergenic manufacturers submitted 46 fewer reports (FY11-182).
 - The number of reports involving product not meeting specifications, decreased from 169 in FY11 to 112 in FY12. The majority (98%) related to precipitate discovered in allergenic extracts, which decreased from 159 in FY11 to 110 in FY12.
 - The number of reports involving stability failures decreased from six in FY11 to one in FY12.
 - The number of reports involving labeling increased from six in FY11 to 22 in FY12. The majority involved the expiration date missing from the label.
- Blood derivative manufacturers submitted 18 more reports (FY11-77).
 - The number of reports related to process controls increased from 16 in FY11 to 25 in FY12.
 - The number of reports related to process/procedures not performed or performed incorrectly increased from nine in FY11 to 19 in FY12, specifically due to equipment not performing properly, which increased from 6 in FY11 to 13 in FY12.
- Licensed in-vitro diagnostic manufacturers submitted 26 more reports (FY11-102).
 - The number of reports related to quality control and distribution increased from 34 in FY11 to 51 in FY12. The majority related to the consignee receiving products upside down or sideways within the shipping container.
 - The number of reports related to the product specifications increased from 37 in FY11 to 49 in FY12. The majority related to leaking vial or container due to loose or unsecure closures (FY11-1, FY12-16).
- Licensed HCT/P manufacturers (351 HCT/P) submitted three more reports (FY11-14).
 - In FY11, the reports involved product specifications (5), labeling (4), incoming material (3), process controls (1), and testing (1). In FY12, the reports involved product specifications (8), labeling (6), process controls (1), and testing (2).

**Total BPD Reports by Manufacturing System
Licensed Non-Blood Establishments**

Table 24

Manufacturing System	Allergenic	Blood Derivative	In Vitro Diagnostic	Vaccine	351 HCT/P	TOTAL	
Product Specifications	112	32	49	126	8	327	50.7%
Quality Control & Distribution	0	11	51	45	0	107	16.6%
Labeling	22	9	5	22	6	64	9.9%
Process Controls	0	25	13	22	1	61	9.5%
Testing	1	7	5	18	2	33	5.1%
Incoming Material	1	11	3	16	0	31	4.8%
Miscellaneous	0	0	2	20	0	22	3.4%
Total	136	95	128	269	17	645	100%

IV. HCT/P Deviation Reports Submitted by Manufacturers of 361 HCT/Ps

The deviation reporting requirement for HCT/Ps regulated solely under section 361 of the PHS Act and 21 CFR Part 1271 became effective on May 25, 2005. Cellular HCT/Ps includes hematopoietic stem/progenitor cells derived from peripheral and cord blood, therapeutic cells and autologous pancreatic islet cells. Tissue HCT/Ps includes, but is not limited to, fascia, cartilage, bone, ligament, tendon, vascular graft, tooth pulp, cornea, sclera, whole eye, limbal graft, skin, heart valve, dura mater, pericardium, amniotic membrane, nerve, parathyroid tissue, placenta, spinal cord, testicular tissue, trachea, and cardiac tissue (non-valved).

Manufacturers of 361 HCT/Ps submitted three more reports in FY12 than in the previous fiscal year (FY11-247) (See Table 2).

- There were 21 fewer reports involving cellular HCT/Ps submitted than in the previous fiscal year (FY11-141, FY12-120).
 - The number of reports involving processing and process controls decreased from 74 in FY11 to 59 in FY12, specifically, reports of contamination or potential contamination during processing, which decreased from 71 in FY11 to 59 in FY12.
 - The number of reports involving receipt, pre-distribution, shipment and distribution decreased from 52 in FY11 to 46 in FY12. The number of reports involving distribution of product that was contaminated or potentially contaminated was similar to the reports we received in FY11 (FY11-48, FY12-45).
- There were 24 more reports involving tissue HCT/Ps submitted than in the previous fiscal year (FY11-106, FY12-130).
 - The number of reports involving donor testing decreased from 41 in FY11 to 17 in FY12.
 - The number of reports involving unacceptable samples used for testing decreased (FY11-36, FY12-14). In FY12, most of these involved using filtered samples for testing.
 - The number of reports involving processing and process controls increased from eight in FY11 to 18 in FY12. The number of reports involving contamination or potential contamination during processing increased (FY11-6, FY12-12).
 - The number of reports involving donor screening increased from 17 in FY11 to 39 in FY12. The number of reports in which the donor medical history interview was performed incorrectly increased from 16 in FY11 to 34 in FY12. Most of these were discovered as a result of an audit of the medical history interview process.
 - The number of reports involving donor eligibility increased from 26 in FY11 to 37 in FY12. There were 16 more reports involving the acceptance of ineligible donors (FY11-21, FY12-37). In FY12, 24 of these reports involved risk factors, clinical or physical evidence identified, and 11 reports involved incorrectly evaluating or not evaluating the donor for plasma dilution.

**Total Reports by Manufacturing System
361 HCT/P Establishments**

Table 25

HCT/P Deviation Code	Cellular HCT/P	Tissue HCT/P	Total	
Processing and Processing Controls	59	18	77	30.8%
Receipt, Pre-Distribution, Shipment & Distribution	46	3	49	19.6%
Donor Screening	1	39	40	16.0%
Donor Eligibility	0	37	37	14.8%
Donor Testing	1	17	18	7.2%
Supplies and Reagents	8	4	12	4.8%
Labeling Controls	1	6	7	2.8%
Recovery	1	3	4	1.6%
Environmental Control	1	2	3	1.2%
Storage	1	1	2	0.8%
Equipment	1	0	1	0.4%
Total	120	130	250	100%

V. Attachments

- 1 – Table-Number of BPD Reports by Type of Blood and Plasma Establishment
- 2 – List of BPD Codes for Blood and Plasma Establishments
- 3 – Table-Number of BPD Reports by Type of Licensed Non-Blood Establishment
- 4 – List of BPD Codes for Licensed Non-Blood Establishments
- 5 – Table-Number of HCT/P Deviation Reports by Type of 361 HCT/P Establishment
- 6 – List of HCT/P Deviation Codes for 361 HCT/P Establishments
- 7 – List of Tables

VI. References

1. Guidance for Industry - Biological Product Deviation Reporting for Blood and Plasma Establishments 10/18/2006
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm073455.htm>
2. Guidance for Industry - Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components 10/18/2006
<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/General/ucm163893.htm>